Nos. 19-16636, 19-16708

In the United States Court of Appeals for the Ninth Circuit

EDWIN HARDEMAN,

Plaintiff-Appellee/Cross-Appellant,

v.

MONSANTO COMPANY,

Defendant-Appellant/Cross-Appellee.

On Appeal from the United States District Court
for the Northern District of California at San Francisco

BRIEF OF AMICUS CURIAE AMERICAN ASSOCIATION FOR JUSTICE IN SUPPORT OF PLAINTIFF-APPELLEE/CROSS-APPELLANT

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

INTEREST OF AMICUS CURIAE[1]

The American Association for Justice (AAJ) is a national, voluntary bar association established in 1946 to strengthen the civil-justice system, preserve the right to trial by jury, and protect access to the courts for those who have been wrongfully injured. With members in the United States, Canada, and abroad, AAJ is the world's largest plaintiff trial bar.

As this brief details, in the years since this Court's decision in *Wyeth v. Levine*, 555 U.S. 555 (2009), manufacturers have attempted to curtail plaintiffs' state-law rights by arguing for an expansive theory of conflict preemption that would preempt failure-to-warn state law based on only hypothetical conflicts with federal law. These attempts have continued even after the Supreme Court's recent decision reaffirming *Wyeth* in *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019). Based on its members' experience with pesticide-related tort litigation—and its organizational concern for the development of the law in this area—AAJ is well-positioned to explain why the expansion of federal preemption Monsanto urges in this case is both ill-conceived and contrary to precedent.

[1] All parties consent to the filing of this brief, and no counsel for any party authored it in whole or in part. Apart from the amicus curiae, no person, party, or party's counsel contributed money intended to fund the brief's preparation and submission.

INTRODUCTION AND SUMMARY OF ARGUMENT

Impossibility preemption is, as the Supreme Court has time and again made clear, "a demanding defense." *Wyeth v. Levine*, 555 U.S. 555, 573 (2009). Federal conflict preemption does not exist where there is only "a hypothetical or potential conflict" between state and federal law. *Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982). Instead, where conflict preemption is alleged, a state's law is only preempted "to the extent that it *actually* conflicts with federal law." *English v. General Electric Co.*, 496 U.S. 72, 79 (1990) (emphasis added); *see also Rice*, 458 U.S. at 659 (requiring that the federal and state laws must "irreconcilably conflic[t]"). And when a party asserts that its state-law obligations are preempted because it is impossible to comply with both state and federal law, that party must demonstrate that it was actually "not lawful under federal law . . . to do what state law required." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011).

The Supreme Court has, over the last decade, repeatedly reinforced this fundamental standard. Starting with *Wyeth*, the Court has held that impossibility preemption does not foreclose state-law failure-to-warn claims simply because a federal agency regulates product labeling. Instead, what matters when a manufacturer attempts to knock out state-law claims with an impossibility-preemption defense is whether the manufacturer could have altered its label to comply with the state-law obligation or whether federal law prohibited such a

change. *See Wyeth*, 555 U.S. at 568–73. And, given the historic role that state law plays in regulating health and safety and penalizing manufacturers for failing to warn consumers of the risks associated with their products, establishing impossibility requires a manufacturer to present "clear evidence" that complying with state law would necessarily force it to violate federal law. *See id.* at 571.

In the years since *Wyeth*, however, manufacturers (with increasing success) pressed lower courts to construe *Wyeth*'s "clear evidence" requirement as a mandate for freewheeling speculation over whether compliance with state law would *potentially* also violate federal law—precisely the kind of "hypothetical or potential conflict" long rejected by the Court. *Rice*, 458 U.S. at 659. As we explain below, just last term the Supreme Court put an end to this improper approach to impossibility preemption. *See Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019). When it comes to state-law failure-to-warn claims, the Court emphasized, "'the possibility of impossibility is not enough.'" *Id.* at 1678 (internal alterations omitted). Impossibility preemption can only bar state-law claims where "there is an actual conflict between state and federal law such that it was impossible to comply with both." *Id.* at 1679.

Applying these settled preemption principles, the district court was right to reject Monsanto's attempt to foreclose the state-law failure-to-warn claims in this case. Under *Merck*'s two-part test for establishing impossibility, a manufacturer must show through clear evidence that that it "fully informed" the agency "of the

justifications for the warning required by state law," and also that the agency, having been so informed, "would not approve a change to the [] label to include that warning." *Merck*, 139 S. Ct. at 1672.

Monsanto did neither here. It could not have fully informed the agency about Roundup's safety because—by the company's own admission—it refused to perform studies on the product's safety and focused its efforts on suppressing or ignoring information that might call Roundup's safety into question. And Monsanto likewise came nowhere close to showing that the EPA actually rejected the proposed warning. The EPA's most recent formal actions were to *approve*, not reject, warning labels on pesticide products containing glyphosate.

Given the demanding standard required to establish impossibility preemption, the district court's denial of Monsanto's impossibility-preemption defense should be affirmed. Monsanto's position, if adopted by this Court, would close the courthouse doors to many Americans who have been harmed by unreasonably dangerous products. It would also shield manufacturers from any accountability for marketing unsafe products and instead incentivize them to divert their resources to pressuring regulatory agencies for some basis to argue impossibility preemption. At bottom, Monsanto's bid for immunity is based not on federal law but instead on informal agency actions or even inaction. The Supremacy Clause, as the Supreme Court has repeatedly made clear, demands more.

ARGUMENT

I. The Supreme Court's settled approach to impossibility preemption requires that failure-to-warn claims be allowed to proceed unless a manufacturer can clearly show actual impossibility.

The Supreme Court's demanding test for impossibility preemption takes its cue from the text of the Supremacy Clause and our federalist system. Under the Supremacy Clause, state law is preempted only by federal law "made in Pursuance" of the Constitution—not by extratextual considerations that may require speculation or hypothesis. 1994 U.S. const., art. VI, cl. 2. That is why any preemption analysis "should not be [a] freewheeling judicial inquiry into whether a state statute is in tension with federal objectives, but an inquiry into whether the ordinary meanings of state and federal law conflict.'" *Wyeth*, 555 U.S. at 588 (Thomas, J., concurring in judgment) (internal quotation marks and citation omitted). When it comes to impossibility preemption, in other words, "state and federal law conflict where it is 'impossible for a private party to comply with both state and federal requirements.'" *Mensing*, 564 U.S. at 618 (quoting *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995)).

A. In *Wyeth*, the Court made clear that impossibility preemption is a particularly demanding defense against state-law failure-to-warn claims.

In *Wyeth*, the Supreme Court announced a series of cornerstone principles that govern the analysis when a manufacturer argues that it is impossible for it to comply with certain state-law labeling obligations without also violating its federal labeling

duties. 555 U.S. at 573. There, the plaintiff sued a drug manufacturer for failing to add a warning regarding the risk of gangrene developing from a particular way of administering a drug. *Id.* at 571. The manufacturer argued that it could not have adopted the warning because federal regulations prevented it from changing its drug's label.

The Court rejected Wyeth's "cramped reading" of the regulation, and held that the failure-to-warn claim was not preempted. *Id.* at 570–71. The Court noted that the federal agency's regulatory process permitted manufacturers to add new warnings to their labels, which meant that Wyeth "could have . . . added a stronger warning" about the drug in question. *Id.* at 568, 570. And the Court reinforced this no-preemption position by recognizing that it is the *manufacturer's* primary responsibility—not an agency's—to ensure its label is accurate and its product is safe. *Id.* at 568–73; *see also Bates v. Dow*, 544 U.S. 431, 438–39 (2005) (noting that "manufacturers have a continuing obligation to adhere to FIFRA's labeling requirements"). In so holding, the Court noted that it was true an agency could act to reject those changes. 555 U.S. at 571. But the mere possibility that an agency *might* reject a label change was not enough to trigger impossibility preemption. *Id.* at 571. Instead, the Court explained that impossibility preemption in a failure-to-warn case would be unavailable unless there was "clear evidence" that the agency "would not have approved [the] change" in question. *Id.* at 571.

In the years since *Wyeth*, that final observation sparked a novel breed of "hypothetical impossibility" preemption. Manufacturers in post-*Wyeth* failure-to-warn cases began advancing a theory of preemption that did not turn on actual impossibility—whether a manufacturer could in fact have added particular warnings to its label—but instead on hypothetical impossibility—whether the manufacturer was right not to include the warning because the FDA *could have* and *would have* rejected it. *See, e.g.*, *Forst v. SmithKline Beecham Corp.*, 639 F. Supp. 2d 948 (E.D. Wis. 2009); *Dorsett v. Sandoz*, 699 F. Supp. 2d 1142 (C.D. Cal. 2010); *Lofton v. McNeil Consumer & Specialty Pharms.*, 682 F. Supp. 2d 662 (N.D. Tex. 2010); *Hunt v. McNeil Consumer Healthcare*, 6 F. Supp. 3d 694 (E.D. La. 2014); *Koho v. Forest Labs.*, 17 F. Supp. 3d 1109 (W.D. Wash. 2014).

Several of these cases show just how far some courts strayed from the "counsel of restraint" that should control in any impossibility preemption inquiry. *Exxon Corp. v. Gov. of Maryland*, 437 U.S. 117, 131 (1978). In *Forst*, for example, a manufacturer pointed to "the amount of interaction it had with [an] agency" and the agency's "repeated review" of a product's safety data without requiring any new warning as "clear evidence" of preemption. 639 F. Supp. at 954. And in other cases, manufacturers focused on agency rejections of citizen petitions to argue for "clear evidence that the FDA would not have approved a change." *Dorsett*, 699 F. Supp. at 1157; *see also Lofton*, 682 F. Supp. at 677–78. As these cases illustrate, the term "clear evidence" had, for

some, become a license to construct elaborate counterfactual scenarios in which the whole range of an agency's actions—sometimes spanning the course of decades, *see, e.g.*, *Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 392–96 (7th Cir. 2010)—is mined for hints of regulatory intent.

B. The Court in *Merck* decisively rejected manufacturer attempts to establish "clear evidence" through hypothetical impossibility.

Impossibility preemption, however, does not deal in hypotheticals. And in *Merck*, the Supreme Court firmly shut the door on manufacturer efforts to treat *Wyeth* as a license for uncabined speculation based on a wide—and ever-increasing—assortment of contextual clues. There, the Court made clear that the question at the heart of the impossibility preemption inquiry in failure-to-warn cases—"agency disapproval"—is a "tightly circumscribed legal analysis." 139 S. Ct. at 1680. To answer it, "the judge must simply ask himself or herself whether the relevant federal and state laws 'irreconcilably conflict.'" *Id.* at 1679 (internal alterations omitted).

This understanding follows from settled preemption principles. It is "not enough," the Court reiterated, for there to be a "'possibility of impossibility.'" *Id.* at 1678 (emphasizing that, "where the laws of one sovereign permit an activity that the laws of the other sovereign restrict or even prohibit," there is no impossibility preemption). Instead, impossibility exists only where federal law *actually* "prohibit[s] the [] manufacturer from adding any and all warnings to the [] label that would

satisfy state law." *Id.* And that remains true, the Court held, even where an agency still has the "authority to reject labeling changes" to a product. *Id.* at 1677. Regardless of an agency's authority, the manufacturer bears the "ultimate responsibility for its label"; it therefore cannot avoid "state laws that would penalize [it] for failing to warn consumers of the risks" associated with its product without clearly showing that compliance would in fact force it to violate federal law. *Id.* at 1677.

The Court in *Merck* also provided straightforward guidance on how to perform this impossibility-preemption inquiry. Although the Court chose not to "further define *Wyeth*'s use of the words 'clear evidence' in terms of evidentiary standards," it identified the only type of evidence that could count: those "agency actions" taken pursuant to congressionally delegated authority. *Id.* at 1679 (noting that preemption "takes place only when and if the agency is acting within the scope of its congressionally delegated authority") (internal quotations and alterations omitted). And the Court further defined those specific forms of agency action that, under relevant federal law, could trigger impossibility preemption as including disapproval of a warning (1) "by means of notice-and-comment rulemaking setting forth labeling standards," (2) "by formally rejecting a warning label that would have been adequate under state law," or (3) "with other agency action carrying the force of law." *Id.*

C. Under *Merck*, establishing impossibility requires a manufacturer to show that it both fully informed an agency of a product's risks *and* that the agency nonetheless rejected a change to the label.

The Court's analysis in *Merck* established a clear two-step framework for determining whether a product manufacturer has met the "demanding defense" of impossibility preemption. *Id.* at 1672, 1678 (internal quotation marks omitted). *First*, a court must determine whether a manufacturer "fully informed" an agency of a product's risks; if it failed to do so, the inquiry stops there and no impossibility preemption can exist. *See* 139 S. Ct. at 1678. *Second*, if (and only if) the agency *was* fully informed of a product's risks, the manufacturer must then show that the agency, acting within the scope of its lawful authority, "would not approve" a change to a product's label. *Id.* In those circumstances—and only those circumstances—is a court justified in reaching a conclusion that state-law failure-to-warn claims are foreclosed.

The Third Circuit's recent decision in *In re Avandia Marketing, Sales and Products Liability Litigation* illustrates how this approach works in practice. *See* 945 F.3d 749, 756 (3d Cir. 2019). There, a manufacturer sought to bar state-law failure-to-warn claims under an impossibility-preemption defense by arguing first that it "fully informed" the agency about the product's safety risks because it "provided all 'material' information" to the agency and second that the agency had actually "rejected the proposed warning." *Id.* at 759.

The Third Circuit rejected both claims, holding that the manufacturer had "failed to satisfy either prong of *Merck*'s two-prong test." *Id.* at 758. For starters, the court explained that the manufacturer had "not shown" that it fully informed the agency "of the justification[] for the warning required by state law" because the agency itself had found the information provided to be "inadequate" and informed the manufacturer that it "needed to submit various data and information in order to address the deficiency." *Id.* The manufacturer had argued that none of the additional requested information was "'material' to its proposed warning," but the Third Circuit flatly dismissed this argument. A manufacturer "is not the arbiter of which data and information is or is not 'material'" to an agency's decision to approve or reject a change to a [product's] label. *Id.* at 759. Instead, it is the agency that can "determine what information is 'material' to *its own* decision to approve or reject a label[]ing change." *Id.* And, the Third Circuit went on to explain, the question of whether an agency was fully informed must be "tethered in time" to the question of whether the agency "indeed rejected the proposed warning." *Id.* Were it otherwise, "the 'fully informed' prong of the test espoused in *Merck* would be rendered superfluous." *Id.*

The court also rejected the manufacturer's effort to show that the agency actually "rejected the proposed warning." *Id.* at 759–60. The manufacturer attempted to point the court to an agency letter stating that the manufacturer's

request for a label change was "not approvable." *Id.* But the court explained that the agency's refused to approve the label "because the information presented" was "inadequate"—not because the agency "was unconvinced of the need for a strong warning." *Id.* at 759. "At most," the court explained, the letter indicated that it was "*possible*" that the agency "could have rejected the label change *after* receiving the various data and information it requested." *Id.* at 760. But, the court reiterated, "the possibility of impossibility is not enough." *Id.* (internal alterations omitted) (quoting *Merck*, 139 S. Ct. at 1678).

II. Under the controlling impossibility-preemption framework, Monsanto failed to meet its demanding burden.

Given the above settled framework, Monsanto's arguments in support of impossibility preemption cannot succeed.[2] Just as in *Avandia*, because Monsanto failed to fully inform the EPA of Roundup's risks and failed to present evidence that

[2] Because Monsanto advances several arguments in support of its impossibility-preemption defense, this brief focuses on those. However, given that the Supreme Court in *Bates* foreclosed these arguments in the FIFRA context, this Court need not reach the merits of Monsanto's impossibility-preemption defense at all. *See* Hardeman Br. at 33, 43–44; *see also* 544 U.S. at 459 (Thomas, J., concurring in the judgment in part and dissenting in part) (noting that *Bates* "comports with this Court's increasing reluctance to expand federal statutes beyond their terms through doctrines of implied pre-emption"). And beyond the statutory text, the existence of regulations authorizing agency pre-approval for some pesticide labeling does not create any basis for impossibility preemption where, among other things, FIFRA permits states to ban the sale of pesticides outright on their own authority. *See* Hardeman Br. at 33 (citing 7 U.S.C. §136v(a)).

the agency specifically rejected a proposed warning label, it "has failed to satisfy either prong of *Merck*'s two-prong test." 945 F.3d at 758.

A. Monsanto did not "fully inform" the EPA of Roundup's risks.

Consider first Monsanto's argument that it fully informed the EPA of Roundup's risks. It first relies (at 34) on outdated EPA reviews of the science on glyphosate to argue that it "fully informed" the agency about Roundup. And then, falling back, it suggests that, even if these older reviews are insufficient, a recent informal EPA letter (dated after the trial in this case ended) stating that glyphosate alone is "not likely to be carcinogenic to humans" demonstrates that the agency has been fully informed within the meaning of *Merck*.

Neither claim is correct. Monsanto could not have fully informed the EPA of the justifications for the kind of warning that might have prevented Hardeman and others' injury, because—as plaintiffs proved below, ER8—it has refused to perform studies on its own product's safety and has instead focused its efforts on suppressing or ignoring information that might call it into question, *see* Hardeman Br. at 24–30. It is principally the job of Monsanto, not the EPA, to evaluate the safety of its own product and inform the agency about what it knows. 40 CFR §§ 159.184(a), (b); *see Bates*, 544 U.S. at 438 (noting that manufacturers "must submit . . . supporting data" and "have a continuing obligation to adhere to FIFRA's labeling requirements"). But as the district court found, Monsanto presented "minimal evidence" that the

company *itself* was "interested in getting to the bottom of" repeated claims that its product causes people to get sick. ER8.

Hardeman proved at trial that the EPA was not informed—fully or otherwise—about any potential dangers of Roundup. The EPA has *no* data from Monsanto about the safety of glyphosate formulations like Roundup that include surfactants, and has explained that it is still studying "whether formulation components, such as surfactants, increase the toxicity of glyphosate formulations." PSER489–91; *see also* Hardeman Br. at 46–48. In its most recent Interim Registration Review Decision, the agency only confirmed its conclusion that glyphosate *alone* is "not likely to be carcinogenic to humans." EPA, Glyphosate: Interim Registration Review Decision at 10 (Jan. 22, 2020), https://bit.ly/2wnw9Mp.

Neither is the agency fully informed of the risks of glyphosate alone. As the district court noted, the agency itself has said its conclusions about glyphosate were not "'definitive.'" *See* Order Denying Motion to Dismiss, Case No. 3:16-cv-00525-VC, Dkt. 34 at 4; *see also* PSER306. And as even the government notes, the EPA's "glyphosate registration review process" in fact "remains ongoing." U.S. Br. at 9.

Monsanto not only failed to "fully inform" the EPA of issues with Roundup, but also ignored safety issues with the product and failed to inform the EPA about what it did discover. Whenever a pesticide manufacturer "has additional factual information regarding unreasonable adverse effects on the environment of the

pesticide," including effects on people, the manufacturer "shall" inform the EPA. 7 U.S. Code §136d(a)(2); 40 C.F.R. § 159.152. Yet Monsanto did not supply the EPA with its own toxicologist's negative reports suggesting Roundup was more dangerous to humans than glyphosate alone and urging the company to conduct further study, which it has repeatedly refused to do. PSER400; PSER257–58; PSER 244; see 40 C.F.R. § 159.152.

Monsanto's main strategy is to sidestep this failure of proof. It suggests that glyphosate and Roundup are synonymous—and so pose identical dangers. In its view, because the EPA knew about the risks associated with glyphosate, it likewise must have known about the risks associated with Roundup. Monsanto Br. at 5 n.1. But Roundup and glyphosate are not synonymous. Roundup is a pesticide formulation containing both glyphosate and chemical surfactants that allows glyphosate to penetrate much farther into cells than it would otherwise be able to. ER2289. As a result, it is more toxic than glyphosate by itself and so needed to be specifically tested by Monsanto to determine its safety. ER2289.

The record in this case confirm the point. At trial, expert studies showed Roundup was at least "ten times more genotoxic than glyphosate." ER573–77. And additional evidence revealed that Monsanto itself *knew* Roundup was significantly more toxic to humans than glyphosate alone, and yet acted to suppress or distort the

existing science. PSER222; PSER234-37; PSER239; PSER 244; PSER257–58; PSER373–74; PSER283–84.

This setup demonstrates why Monsanto cannot satisfy the first step under *Merck*'s framework. By its own admission, Monsanto has never done the tests necessary to fully inform the agency of Roundup's risks and so it cannot show that the EPA was "fully informed" about the product's risks. *In re Avandia*, 945 F.3d at 759. That alone is enough to preclude impossibility preemption.

B. Monsanto failed to show that the EPA "would not approve a change" to Roundup's label warning users about the product's safety hazards.

And, were it even necessary, Monsanto also cannot meet *Merck*'s second requirement to show that the EPA would have rejected any proposed changes to Roundup's label to include a warning. 139 S. Ct. at 1672. For some of the same reasons the EPA cannot be said to be "fully informed" of Roundup's danger—including the agency's own admission that glyphosate formulations like Roundup merit further study, see Part II A above—Monsanto cannot demonstrate that the EPA would have not have approved a warning. As noted above, the government itself admits that the EPA's own glyphosate "review process" remains ongoing. U.S. Br. at 9. And the manufacturer's remaining argument on this score—an informal EPA letter—fails as a matter of law. Monsanto Br. at 35. The August 2019 letter cannot satisfy the approval requirement because it applies only to glyphosate, not Roundup, and in

any case does not constitute an exercise of the agency's congressionally-delegated power, as required by *Merck*.

What's more, even assuming glyphosate and Roundup *are* synonymous, the EPA's most recent formal actions show, if anything, that the agency would have approved, not rejected, the addition of a warning label to Roundup's packaging. As the government acknowledges, the EPA's most recent formal actions relating to glyphosate warnings were to *approve* the addition of warnings to those products. U.S. Br. at 18 n.14. Although the government asserts—without citation—that these approvals were a "mistake[]," *id.*, it is the formal "agency actions" that matter for impossibility preemption, *see* 139 S. Ct. at 1679. That itself, standing alone, is enough for Monsanto's preemption argument to fail.

Nor can an informal letter about these mistaken warnings save Monsanto. Monsanto Br. at 34–36. The August 7, 2019 letter—sent long after the jury returned a verdict in this case—suggests that pesticide products bearing warnings "where the only basis for the warning is glyphosate" would be misbranded and would need to be removed.

But regardless of its contents, this letter is not an exercise of the EPA's congressionally delegated authority and so is incapable of exerting preemptive force. As *Merck* makes clear, when it comes to impossibility preemption, only agency actions taken "within the scope of [an agency's] congressionally delegated authority" can

create preemption. 139 S. Ct. at 1679; *see also id.* at 1683 at n.* (Thomas, J., concurring) (noting that "the only proper agency actions are those 'that are set forth in, or necessarily follow from, the statutory text,' and they must have the force of law to be pre-emptive"). And under FIFRA, the EPA's formal method for approving or disapproving label warning does not include the type of letter Monsanto identifies. To the contrary, if the agency determines that a pesticide "does not comply with" FIFRA, it may "issue a notice" either "cancel[ing] its registration or … chang[ing] its classification, or . . . hold a hearing to determine whether or not its registration should be canceled or its classification changed." 7 U.S.C. § 136d(b). It may also seize or condemn the products, 7 U.S.C. § 136k(b); issue orders to stop a pesticide's sale or use, 7 U.S.C. § 136k(a); or impose certain penalties for unlawful acts, 7 U.S.C. 136j. The August 2019 EPA letter takes none of these congressionally-delegated agency actions—it merely makes a request, and that is not enough.

Indeed, courts have long held that similarly informal agency communications cannot satisfy the impossibility preemption standard. In *Fellner v. Tri-Union Seafoods, LLC*, 539 F.3d 237, 254–55 (3d Cir. 2008), for instance, an informal agency letter written by the agency's commissioner offered the opinion that a warning on a tuna can would constitute mislabeling—but, like the EPA's letter, did not take any action in exercise of the agency's authority. *Id.* The letter was held to have no preemptive effect. *Id.* at 255–56. An agency "must actually exercise its authority in a manner in

fact establishing the state warning as false or misleading under federal law." *Id.* at 255. "[I]nformal views expressed in [a] Commissioner's letter will not preempt [a] lawsuit." *Id.*; *see also In re Avandia*, 945 F.3d at 760 (noting that "informal phone conversations" or stock warnings about potential misbranding are not the kind of agency action *Merck* contemplates); *Gustavsen v. Alcon Labs., Inc.*, 903 F.3d 1, 14 (1st Cir. 2018) (rejecting reliance on "sporadic" agency actions "made by mid-level [agency] scientists, or even a single 'reviewer'" because it is "far from clear" that they "reflect the 'fair and considered' judgment of the agency").

So it is here. Because the August 2019 EPA letter was written by an individual at the Office of Pesticide Programs and took no formal action, it is insufficient to trigger impossibility preemption.

C. Monsanto's hypothetical impossibility argument would undermine both *Merck* and FIFRA.

At bottom, Monsanto's impossibility-preemption arguments track the hypothetical-impossibility approach to preemption that the Court in *Merck* firmly rejected. Monsanto suggests that if it *were* to supplement its label with a warning about the specific risks of Roundup, *then* the EPA would consider the product misbranded. But the EPA has never had occasion to consider the evidence of Roundup's danger to consumers; it has never seen the research about Roundup, which Monsanto has refused to conduct; and the agency's research on glyphosate

alone is ongoing and incomplete. *Merck* squarely rejects this speculative approach to preemption.

Adopting Monsanto's position would not only contravene *Merck*, but also reward manufacturers for sticking their heads in the sand—including those that refuse to conduct studies on their own products' safety. In Monsanto's case, the company's resistance to investigate product safety persisted over suggestions to conduct studies from its own toxicologist, even in the face of mounting evidence that Roundup was hurting people. Under Monsanto's view of federal law, only at the 15-year statutory re-registration mark would a product's label be reviewed by the EPA—and a manufacturer would have no reason to provide the agency with studies it does not itself conduct.

FIFRA was not designed to work in that way. Under the statute, just like the FDCA, it is the *manufacturer's* duty to ensure on an ongoing basis that its products are safe. 40 CFR §§ 159.184(a), (b); *see Bates*, 544 U.S. at 438. And that is particularly important where, as here, the agency itself is reliant on the manufacturer to bring safety issues with a product to its attention. *Bates*, 544 U.S. at 438. As Justice Thomas noted more than a decade ago in *Wyeth*, that a manufacturer "may not market a [product] without federal approval" does not mean that "federal approval gives [the manufacturer] the unfettered right, for all time, to market its [product] with the specific label that was federally approved." 555 U.S. at 592 (Thomas, J., concurring).

Monsanto's position on impossibility preemption, if adopted by this Court, would close the courthouse doors to many Americans who have been harmed by unreasonably dangerous products. The immunity Monsanto seeks is not based on federal law, as the Supremacy Clause demands, but on informal agency actions or, even, agency inaction. But allowing manufacturers to shield themselves from any accountability for marketing unsafe products based on such informal grounds would incentivize manufacturers to re-direct their resources away from ensuring the safety of their products and toward campaigns designed to pressure regulatory agencies—and even individual regulators—for some basis to argue impossibility preemption. Neither the Supreme Court's preemption case law nor FIFRA permits such a result.

CONCLUSION

The district court's denial of Monsanto's impossibility-preemption defense should be affirmed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) because this motion contains 5,018 words, excluding the parts exempted by Rule 32(f). This brief complies with the typeface requirements of Rule 32(a)(5) and the type-style requirements of Rule 32(a)(6) because it has been prepared in proportionally spaced typeface using Microsoft Word in 14-point Baskerville font.

s/Matthew W.H. Wessler
Matthew W. H. Wessler

CERTIFICATE OF SERVICE

I hereby certify that on March 23, 2020, I electronically filed the foregoing brief with the Clerk of the Court for the U.S. Court of Appeals for the Ninth Circuit by using the CM/ECF system. All participants are registered CM/ECF users, and will be served by the appellate CM/ECF system.

s/Matthew W.H. Wessler
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